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REMARKS

Claims 1-7, 9-19 are pending in the present application. Claims 14-19 have been withdrawn. Claims 1, 3, 4, 9, 12, and 13 have been amended. Claim 8 has been canceled.

The support for the amendments are located in the claims as filed. The support for Claim 1 is found in the claims as filed and page 3, lines 33-34, page 5, lines 27-29, page 7, lines 20-22, and page 8, lines 2-3 of the present specification. The support for Claim 12 is found in the claims as filed and page 3, lines 33-34, page 5, lines 27-29, page 7, lines 20-22, page 8, lines 2-3, and page 17, lines 3-4 of the present specification. The support for Claim 13 is found in the claims as filed and page 17, line 5 of the present specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

The Rejection Under 35 USC § 112, second paragraph

The Examiner has rejected Claims 1-13 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection based on the remarks contained herein.

The Examiner states that Claims 1, 11, and 12 recite the term "safe and effective amount" and that the specification states that there are multiple uses and effects and it is unclear what amounts are deemed effective for what purpose.

In *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989), the Court held that "the public is entitled to know the scope of the claims but must look to both the patent specification and the prosecution history...". Additionally, in *North American Vaccine, Inc v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993, cert. denied, 511 U.S. 1069 (1994)), the Court stated that "Whether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.".

Applicant respectfully submits that each term objected to is fully defined, described and exemplified in the present specification. Most of the terms referred to are also commonly used terms in the art and would be readily understood by one of ordinary skill. It is not required of Applicant to redefine in the claim each term when it is sufficiently defined in the specification as in the present case.

35 USC § 112 does not require Applicants to redefine in the claim each term when it is sufficiently defined in the specification as in the present case. In the case *In re Fuetterer*, 319 F. 2d 259, 138 U.S.P.Q. (BNA) 217 (C.C.P.A. 1963), the U.S. Court of Customs and Appeals decided a case in which the Examiner had rejected the claim that contained "an **effective amount** ranging from more than incidental impurities". The Examiner stated that it would place an "undue burden...upon the public, to determine the operable proportions" that would enable the public to practice the invention. However, the U.S. Court of Customs and Appeal was not persuaded that any "undue burden" is placed on the public by the appellant's disclosure and rejected the Examiner's contention that the claims were indefinite and ambiguous. 35 U.S.C. 112 clearly indicates, in its first paragraph, that it is the function of the "written description" of the invention to "enable" one skilled in the pertinent art to "make and use" the invention and not that of the claims. This case has been subsequently followed by the C.A.F.C. in *In re Application of Herschler*, 591 F. 2d 693, 200 U.S.P.Q. (BNA) 711 (C.C.P.A. 1979) and *In re Anderson*, 471 F. 2d 1237, 176 U.S.P.Q. (BNA) 331 (C.C.P.A. 1973). The current specification describes safe and effective to mean an amount of a component, high enough to significantly (positively) modify the condition to be treated or to effect the desired result, but low enough to avoid serious side effects (at a reasonable benefit/risk ratio), within the scope of sound medical/dental judgment. (Page 4, lines 6-9) However, Applicants have amended Claim 1 for reasons unrelated to patentability and to allow for prosecution of the current application to proceed forward.

Claims 3, 4, 8, and 9 have been rejected because the term "level" lacks antecedent basis. The claims have been amend to remove this term.

Finally the Examiner states that 12 and 13 are rendered vague and indefinite for reciting "less than about 1%" and "less than about 0.5%". These claims have been amended for reasons unrelated to patentability.

Accordingly, it is respectfully requested that these rejections be reconsidered and withdrawn.

The Rejections Under 35 USC § 102(b)

Claims 1, 3-4 and 12-13 are rejected under 35 USC § 102(a) and 102(e) as being anticipated by Barkalow et al US Patent Application 2002/0131990. The Examiner states that Barkalow et al. discloses an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents wherein the bulk fibers may be wood cellulose. Applicants respectfully traverse this rejection based on the remarks contained herein.

Under § 102, anticipation requires that all the Claim elements appear in a single prior art document. "A Claim is anticipated only if each and every element set forth in the Claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 citing *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987). "The Identical invention must be shown in as complete detail as is contained in the ... Claim." MPEP § 2131 citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2D 1913, 1920 (Fed. Cir. 1989).

The present invention requires in Claim 1 an edible film composition comprising: from about 0.01% to about 25% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent. The Barkalow et al. reference never teaches or suggests from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent.

The present invention cannot be anticipated by this reference. Since Barkalow et al. does not disclose each and every element of the present application, it cannot as a matter of law anticipate the present application.

Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC 103(a) Over Barkalow et al. in view of Yatka et al. US 5,458,892

Claims 1-13 have been rejected under 35 USC 103(a) as being unpatentable over Barkalow et al. in view of Yatka et al. US 5,458,892. The Examiner states that Barkalow et al. discloses an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents wherein the bulk fibers may be wood cellulose. The Examiner states that Yatka et al. discloses a bulking agent that is indigestible dextrin and this can be dried with flavors to encapsulate the flavor. Applicants respectfully traverse this rejection based on the remarks contained herein.

Barkalow et al. discloses pullulan free edible films. Barkalow et al. discloses that the bulk filler agent can include cellulose polymers such as wood. The wood cellulose of the present invention is purified wood cellulose. These materials are highly purified cellulose and comprise more than 99% dietary fiber. (See Page 5, line 8-12). Barkalow fails to teach or suggest purified wood cellulose and a cellulose polymer such as wood would not have the same composition makeup as purified wood cellulose. The Barkalow reference does not disclose or suggest the purified wood

cellulose or an edible film composition comprising: from about 0.01% to about 25% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent. The Barkalow et al. reference never teaches or suggests from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent as described and claimed in the present invention.

Yatka et al. discloses a chewing gum product containing indigestible dextrin. Yatka et al. discloses that is highly preferred to use purified indigestible dextrin, having all of the fermentable components removed. Additionally, Yatka does not teach or suggest the fiber length. Yatka discloses the molecular weight (Column 3, Lines 30-33), the location of specific linkages or bonds (Column 3, lines 5-21), caloric value (Column 3, lines 44-50), and that it is preferable to use a carbohydrate or carbohydrate like food ingredient for chewing gum (Column 1, lines 40-50). The indigestible dextrin in the Yatka reference is being used to provide a bulk sweetener to the chewing gum. The indigestible dextrin of the current invention is used as a source of fiber. One of ordinary skill in the art would not be motivated based on the disclosure of Yatka to use the indigestible dextrin as a fiber source. No where in Yatka does it teach or suggest that by using the indigestible dextrin that there will be an increasing of the film strength of the edible film composition while at the same time maintaining complete and/or rapid film dissolution.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Barkalow and Yatka, one would still fall short of the of Applicants' claimed invention only to arrive at a pullulan free edible film that contains cellulose polymers such as wood and a bulk sweetener indigestible dextrin that does not contribute to dental caries.

The combination of Barkalow and Yatka do not teach or suggest each and every element of Applicants' presently claimed invention i.e. an edible film composition comprising: from about 0.01% to about 25% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent or a film composition that rapidly dissolves in the oral cavity and wherein the composition has from about 0.001% to about 20% by weight of surfactant.

Accordingly, Claims 1-7, 9-13 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

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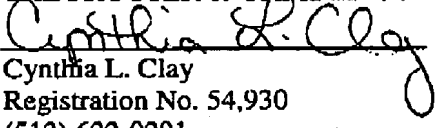
Conclusion

In light of the remarks and amendments presented herein, Applicants respectfully submit Claims 1-13 are allowable over the cited reference. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicant's undersigned attorney for further discussion.

Respectfully Submitted,

THE PROCTER & GAMBLE COMPANY

By


Cynthia L. Clay
Registration No. 54,930
(513) 622-0291

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Customer No. 27752